The following corrections or additions to the January 2006 list were published in the Federal Register in May 2006.

New Approvals

ANADA Number: 200-427

Pioneer Product:	139-192
Trade Name:	Heifermax™ 500 Liquid Premix and Tylan®
Ingredients:	Melengestrol acetate and tylosin phosphate
Sponsor:	Ivy Laboratories, Division of Ivy Animal Health
Approval Date:	April 19, 2006
Status:	Over-the-counter
Route:	Oral
Species:	Beef cattle; heifers fed in confinement for slaughter.
Drug Form:	Type A Medicated Articles for use in combination for the manufacture of two-way Type C medicated feeds.
Concentration:	Heifermax™ 500 - Liquid Type A medicated article containing 500 milligrams melengestrol acetate activity per pound. Tylan® - Type A medicated article containing 10, 40, or 100 grams of tylosin phosphate activity per pound.
Indications:	For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat) and reduced incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes* in heifers being fed in confinement for slaughter.
Tolerance:	21 CFR 556.740 Tylosin: A tolerance of 0.2 part per million is established for negligible residue in uncooked fat, muscle, liver, and kidney in cattle. 21 CFR 556.380 Melengestrol Acetate: A tolerance of 25 parts per billion is established for residues of the parent compound, melengestrol acetate, in fat, of cattle.
Withdrawal:	Zero days

21CFR 558.342

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-075

Trade Name:	Antizol-Vet®
Ingredients:	Fomepizole
Sponsor:	Jazz Pharmaceuticals, Inc.
Approval Date:	April 18, 2006

This application provides for the removal of the 0.9% sodium chloride diluent from this product.

21CFR 522.1004

NADA Number: 106-965

Trade Name:	Tribrissen® 48%
Ingredients:	Trimethoprim, sulfadiazine
Sponsor:	Schering-Plough Animal Health Corp.
Approval Date:	April 26, 2006

This application provides for revised food safety labeling.

21CFR 522.2610

NADA Number: 131-918

Trade Name: Tribrissen® 400 Oral Paste
Ingredients: Trimethoprim, sulfadiazine
Sponsor: Schering-Plough Animal Health Corp.
Approval Date: April 25, 2006

This application provides for revised food safety labeling.

21CFR 520.2611

Change of Sponsor

NADA Number(s): 044-759, 095-543, 095-547, 095-548, 095-549, 098-340, 098-341, 101-628, 101-629, 130-185, 130-661, 130-951, 137-483, 139-473, 140-339, 140-340, 140-533, 140-584, 140-824, 140-843, 140-845, 140-918, 140-919, 141-034, 141-129, 200-075, 200-080, 200-081, 200-082, 200-083, 200-086, 200-089, 200-090, 200-091, 200-092, 200-093, 200-094, 200-095, 200-096, 200-097, 200-143

From: Intervet, Inc.
To: Huvepharma AD
33 James Boucher Blvd.
Sophia 1407
Bulgaria
Drug labeler code: 016592

NADA Number(s): 141-075

From: Orphan Medical, Inc.
To: Jazz Pharmaceuticals, Inc.
3180 Porter Dr.
Palo Alto, CA 94304
Drug labeler code: 068727

Addition of Sponsor

Huvepharma AD
33 James Boucher Blvd.
Sophia 1407
Bulgaria
Drug labeler code: 016592

Jazz Pharmaceuticals, Inc.
3180 Porter Dr.
Palo Alto, CA 94304
Drug labeler code: 068727

Suitability Petition Action

Number:	06P-0093/CP1
Sponsor:	ECO Animal Health
Petition:	Request permission to file an ANADA for a generic new animal drug ivermectin which differs from the pioneer product, Ivomec® 1%, Merial Ltd., NADA 128-409, by the following characteristic(s): The generic will differ in strength (2%) from the pioneer product (1%).
Action:	Denied May 5, 2006.

Notice(s)

The Food and Drug Administration (FDA) is announcing the availability for comments of a draft guidance document for industry (182) entitled ``Pharmacovigilance of Veterinary Medicinal Products; Data Elements for Submission of Adverse Event Reports" (VICH GL42). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The objective of this draft guidance document is to standardize the data for submission of adverse events relating to veterinary medicinal products.

Submit written or electronic comments on the draft guidance by June 1, 2006, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the draft guidance and the docket number [Docket No. 2006D-0170].

For further information contact: Lynn Post, Center for Veterinary Medicine, (HFV-210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9062, e-mail: lynn.post@fda.hhs.gov.

The Food and Drug Administration (FDA) is announcing the availability of draft revised guidance for industry (117) entitled ``Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports (AER's)" VICH GL24. This draft revised guidance, which updates a draft guidance on the same topic for which a notice of availability was published in the Federal Register of December 18, 2000 (the 2000 draft guidance), has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft revised guidance is intended to describe the reporting system for identification of possible adverse events following the use of marketed veterinary medicinal products (VMPs) submitted to the European Union, Japan, and the United States.

Submit written comments on the draft revised guidance by June 1, 2006, to ensure their adequate consideration in preparation of the final guidance document. General comments on agency guidance documents are welcome at any time.

Submit written requests for single copies of the draft revised guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft revised guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the draft revised guidance and the docket number [Docket No. 2000D-1632 (formerly 00D-1632)].

For further information contact: Lynn Post, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9062, e-mail: lynn.post@fda.hhs.gov.

The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for recordkeeping and reports concerning experience with approved new animal drugs. The information contained in the reports required by this regulation enables FDA to monitor the use of new animal drugs after approval and to ensure their continued safety and efficacy.

Submit written or electronic comments on the collection of information by July 18, 2006. Submit electronic comments on the collection of information to: http://www.fda.gov/dockets/ecomments. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

For further information contact: Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.